Iowa Department of Public Health
Rule Changes For 2001

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 9, 2001~~July 4, 2001.

Amend rule **641 ¾ 38.2(136C)** as follows:

Amend the following definition:

"Healing arts screening" means the testing of human beings using ~~X-ray machines~~radiation for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 41.1(3)"a"(7) or listed as an authorized user on a Iowa, U.S. Nuclear Regulatory Commision, or agreement state radioactive materials license.

Delete the definition of "mammogram" and amend the definition of "mammography" as follows:

"Mammography" means the radiography of the breast except as defined in 41.6(1).

Add the following **new** definitions:

"Reportable medical event" means the administration of radioactive material for diagnostic medical use that results in the patient or human research subject (1) receiving greater or less than twenty percent of a prescribed dose; (2) receiving a dose intended for another individual; or (3) receiving a dose that was not prescribed by an authorized user.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2, for normal form radioactive material, where A_1 and A_2 are given in, or may be determined by procedures described in Chapter 39, Appendix E.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

Amend subparagraph **38.8(2)"a"(1)** as follows:

(1) Fees associated with licensing of the possession and use of radioactive materials in Iowa ~~are identical to those~~ shall not exceed those specified in 10 CFR 170.31 ~~entitled "Schedule of Fees for Materials Licenses and Other Regulatory Services."~~.

Amend subrule **38.8(6)** by adopting **new** paragraph as follows:

d. Continuing education late fee. Any individual who will not complete the required continuing education before the continuing education due date and

wishes to submit a plan of correction as set forth in 641—paragraph 42.2(3)"g" paragraph (2), shall submit a fee of $25 along with the written plan of correction.

Amend subrule **38.8(7)** as follows:

a. ~~$15~~ $25 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. $25 for each month for failure to pay ~~annual radiation machine registration or diagnostic radiation operator fee~~ any fee administered by this agency starting ~~the first day of the month after the expiration of the facility's registration or operator's permit to practice~~30 days after the due date of the original notice. This fee is added to the unpaid ~~annual~~ fee.

Amend subrule **38.8** by adopting **new** numbered subrule **38.8(12)** as follows:

38.8(12) Radioactive waste transportation.

a. All shippers of waste containing radioactive materials, transporting waste across Iowa, shall pay the following fee(s) unless the agency is able to obtain appropriate funding from another source (i.e.: federal agency).

1. $1750 per truck for each truck shipment of spent nuclear fuel, high-level radioactive waste or transuranic waste traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of $15 per mile for every mile over 250 miles for the first truck in each shipment.
2. $250 per truck for transport of low-level radioactive waste.
3. $1250 for the first cask and $100 for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste or transuranic waste traversing the state or any portion thereof.
4. $250 for the first railcar and $50 for each additional railcar in the train for transport of low-level radioactive waste.

b. All fees must be received by the agency prior to shipment. The agency will provide each shipper with a "Certificate of Payment of Fees." The certificate must be with the shipment when it enters Iowa and available for inspection by the agency or a representative of the Motor Carrier Safety Division of the Iowa Department of Transportation.

Amend subrule **39.1(3)** as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 10, 2000~~ May 9, 2001.

Adopt **new** subrule **39.1(4)** as follows:

39.1(5) In areas under exclusive federal jurisdiction, nothing in these rules apply to the extent that persons are subject to the regulation by the U.S. Nuclear Regulatory Commission (NRC) or other federal agencies.

Amend subparagraph **39.4(90)"a"(1)** as follows:

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license~~, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone~~.

Amend subrule **39.4(1)** by amending paragraph **"a"** and adding **new** paragraph **"b"**:

~~**39.4(1)**~~**39.4(1)** Additional requirements.

a. In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal or radioactive material are subject to the requirements of 641—Chapter 40.

b. An Iowa radioactive materials license requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored. The office must have at least one full-time employee and a telephone.

Amend subrule 40.1(5) as follows:

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before ~~May 10, 2000~~ May 9, 2001.

Amend subrule **40.26(3),** paragraph **"a"** as follows:

a. Demonstration of the need for and the expected duration of operations in excess of the limit in ~~40.13(1)~~ 40.26(1); and

Amend subrule **40.65(1)** as follows:

40.65(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity~~, as defined in 641—subrule 39.5(2) and appendix E of 641—Chapter 39,~~ shall make arrangements to receive:

Amend paragraph **40.65(1)"b"** as follows:

b. Monitor the external surfaces of a labeled[3] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity~~, as defined in 641—subrule 39.5(2) and Appendix E to 641—Chapter 39~~; and

Amend paragraph **40.65(4)"b"** as follows:

b. External radiation levels exceed the limits of ~~641—paragraph 39.5(15)"i" and 641—paragraph 39.5(15)"j."~~10 CFR 71.47 as set forth in 641—39.5.

Amend subrule **40.111(1)**, paragraph **"f"** as follows:

f. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to ~~641—40.113(136C).~~641—40.112(136C).

Amend subrule **41.1(1)** as follows:

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 9, 2001~~July 4, 2001.

Amend subrule **41.1(2)** by rescinding the following definition:

"Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 41.1(3)"a"(7).

Amend subrule **41.1(3)** as follows:

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control and for having the following minimum test performed ~~every two years~~ by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.
2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.
3. Fluoroscopic: entrance exposure rate (641—41.1(5)"c"), and minimum SSD (641—41.1(5)"f") every two years.

Amend subparagraph **41.1(3)"d"(1)**, as follows:

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment

arrangements shall be submitted to the agency for review and ~~approval~~ verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

Amend subparagraph **41.1(6)"b"(2),** third paragraph, as follows:

Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure.

Amend subrule **41.1(6)** by adopting **new** paragraph **"k"** as follows:

k. Systems used in a clinical (non-surgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3)"d."

Amend subparagraph **41.1(7)"c"(2)** as follows:

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

Amend subrule **41.1(10)"c"** as follows:

c. Operating procedures. Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1 except for 641—41.1(3) and 41.1(10).

Amend subrule **41.2(5)"a"** as follows:

a. A licensee shall provide to the agency a copy of the board certification, the NRC or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as ~~an~~ a visiting authorized user or ~~an~~ a visiting authorized nuclear pharmacist ~~pursuant to 41.2(4)"b"(1) to 41.2(4)"b"(4)~~.

Amend paragraph **41.2(9)"b"(2),** subparagraph **2.** as follows:

2. Review, ~~pursuant to 41.2(4)"b"(1) to 41.2(4)"b"(4),~~ on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

Amend subrule **41.2(14)** and first sentence of paragraph "**a**" as follows:

41.2(14) Records and reports of misadministrations, reportable medical events, and written directives.

a. When a misadministration ~~involves any therapy procedure~~occurs, the licensee shall notify the agency by telephone.

Amend subparagraph **41.2(14)"b"(1)**, the first sentence as follows:

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration and 30 days after discovery of a reportable medical event.

Rescind subparagraph **41.2(14)"c."**

Amend paragraph **41.2(14)"d,"** the first sentence as follows:

d. Each licensee shall retain a record of each misadministration for ten years and each reportable medical event for three years.

Amend subparagraph **41.2(17)"b"(1)** as follows:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on ~~a~~ frequently used ~~setting~~ settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

Amend subrule **41.2(22)**"**b**" as follows:

b. ~~A~~Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

Amend subrule **41.2(41)** as follows:

41.2(41) Use of sealed sources for diagnosis. A licensee shall use the following sealed sources or any sealed source for which the Food and Drug Administration has a "Premarket Approval Application (PMA)" for diagnostic uses in accordance with the manufacturer's radiation safety and handling instructions:

Amend subrule **41.2(41)** by adopting **new** paragraph as follows:

e. Germanium-68 in imaging systems.

Amend subrule **41.2(43)** as follows:

41.2(43) Use of sources for brachytherapy. A licensee shall use the following sources or any sealed source for which the Food and Drug Administration has a "Premarket Approval Application (PMA)" for therapeutic uses in accordance with the manufacturer's radiation safety and handling instructions:

Amend subrule **41.2(67)** as follows:

41.2(67) Training for uptake, dilution, or excretion studies. Except as provided in ~~41.2(75) and~~ 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(31) to be a physician who:

Amend subrule **41.2(68)** as follows:

41.2(68) Training for imaging and localization studies. Except as provided in ~~41.2(75) and~~ 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 41.2(33) to be a physician who:

Amend subrule **41.2(69)** as follows:

41.2(69) Training for therapeutic use of radiopharmaceuticals. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(37) for therapy to be a physician who:

Amend subparagraph **41.2(69)"b"(2)**, paragraph **5.** and add **new** subparagraph **6.** as follows:

5. Use of strontium-89 or samarium-153 for relief of pain in metastatic disease in three individuals; ~~or~~
6. Use of iodine-131 radiolabeled monoclonal antibody for treatment of non-Hodgkin's Lymphoma in three patients; or

Amend subrule **41.2(70)** as follows:

41.2(70) Training for therapeutic use of brachytherapy sources. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user using a brachytherapy source specified in 41.2(43) for therapy to be a physician who:

Amend subrule **41.2(71)** as follows:

41.2(71) Training for ophthalmic use of strontium-90. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user using only strontium-90 for ~~opthalmic~~ ophthalmic radiotherapy to be a physician who

Amend subrule **41.2(72)** as follows:

41.2(72) Training for use of sealed sources for diagnosis. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user using a sealed source in a device specified in 41.2(41) to be a physician, dentist, or podiatrist who:

Amend subrule **41.2(73)** as follows:

41.2(73) Training for teletherapy. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user of a sealed source specified in 41.2(49) in a teletherapy unit to be a physician who:

Amend subrule **41.3(2)** by amending the definition of "radiation therapy physicist" as follows:

"Radiation therapy physicist" means an individual qualified in accordance with ~~41.3(4)"d."~~ 41.3(6).

Amend numbered subparagraph **41.3(18)"a"(4)"2"** as follows:

2. If the absorbed dose rate information required by ~~41.3(18)"a"(8)~~41.3(18)"a"(9) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall be removable only by the use of tools;

Amend numbered subparagraph **41.3(18)"a"(7)"2"** as follows:

2. The device(s) referenced in 41.3(18)"a"(7)"1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if ~~the specifications in 41.3(18)"a"(7)"2"~~field asymmetry cannot be maintained at 10 percent or less.

Amend numbered subparagraph **41.3(18)"e"(1)"3"** as follows:

3. Before medical use under the following conditions:
   - Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and
   - Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, full calibration shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)"e"(1)"3."

Amend numbered subparagraph **41.3(18)"f"(5)"2"** and **"3"** as follows:

2. If all quality assurance parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within ~~two weeks of treatment~~ seven working days; and
3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check within ~~two weeks~~ 20 working days of completion.

Amend subrule **41.6(1)** by amending the definition of "mammography" as follows:

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or
2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

3. Radiography of the breast performed as part of either a breast localization procedure or a post stereotactic clip placement localization procedure.

Amend rule **641¾41.7(136C)** as follows:

641¾41.7(136C) X-ray machines used for ~~mammographically~~ stereotactically guided breast biopsy.

41.7(1) Definitions. In addition to the definitions provided in rule 41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)"a" or 41.7(3)"c") are working together in consultation and in performing ~~mammographically~~ stereotactically guided breast biopsies with a common goal of the patient's benefit.

"~~Mammographically~~ stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

Amend subrule **41.7(2)** as follows:

41.7(2) Registration and application standards and requirements.

a. Each radiation machine used to perform ~~mammographically~~ stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform ~~mammographically~~ stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The ~~mammographically~~ stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform ~~mammographically~~ stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire ~~mammographically~~ stereotactically guided breast biopsy system is evaluated annually by a radiation physicist who meets the requirements of this rule.

Amend subrule **41.7(3)** as follows:

41.7(3) Physicians. Physicians must be qualified according to the setting and their role in performing ~~mammographically~~ stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)"b".
2. Shall have performed at least 12 ~~mammographically~~ stereotactically guided breast biopsies prior to July 1, 1998, or at

least 3 hand-on ~~image~~ stereotactically guided breast biopsies under a physician who is qualified under 41.6(3)"b" and has performed at least 24 ~~mammographically~~ stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME in ~~image~~ stereotactically guided breast biopsy.
4. Shall be responsible for mammographic interpretation, be experienced as noted in "2" above and be experienced in recommendations for biopsy and lesion identification at time of biopsy.
5. Shall be responsible for oversight of all quality control and quality assurance activities.
6. Shall be responsible for the supervision of the radiologic technologist and the medical physicist.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 ~~mammographically~~ stereotactically guided breast biopsies per year or requalify as specified above in 41.7(3)"a"(1).
2. Obtain at least three hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast biopsy every three years.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must have at least three hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.
2. Must have performed at least 12 ~~mammographically~~ stereotactically guided breast biopsies prior to the effective date of these rules, or at least 3 hands-on ~~mammographically~~ stereotactically guided breast biopsy procedures under a physician who is both qualified to interpret mammography according to 41.6(3)"b" and has performed at least 24 ~~mammographically~~ stereotactically guided breast biopsies.
3. Shall be responsible for ~~postbiopsy~~ post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 ~~mammographically~~ stereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.
2. Obtain at least three hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast biopsy every three years.

c. Requirements for a radiologist performing ~~mammographically~~ stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)"b".

2. Initially, must have at least three hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast biopsy.
3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.
4. Must have performed at least 12 ~~mammographically~~ stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on ~~mammographically~~ stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)"b" and has performed at least 24 ~~mammographically~~ stereotactically guided breast biopsies.
5. Must be responsible for mammographic interpretation.
6. Must be responsible for patient selection.
7. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).
8. Must be responsible for the oversight of all quality control.
9. Must be responsible for the supervision of the radiologic technologist and the medical physicist.
10. Must be responsible for ~~postbiopsy~~ post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 ~~mammographically~~ stereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.
2. Obtain at least three hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast biopsy every three years which includes ~~postbiopsy~~ post-biopsy management of the patient.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)"c") performing ~~mammographically~~ stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must have evaluated at least ~~480~~240 mammograms per year in the prior two years in consultation with a physician who is qualified according to 41.6(3)"b".
2. Initially, must have at least 15 hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 ~~image~~ stereotactically guided breast biopsies.
3. Must have four hours of Category 1 CME in medical radiation physics.
4. Must have performed at least 12 ~~mammographically~~ stereotactically guided breast biopsies prior to the effective date of these rules, or at least 3 hands-on ~~mammographically~~ stereotactically guided breast biopsy procedures under a physician

who is both qualified according to 41.6(3)"b" and has performed at least 24 ~~image~~ stereotactically guided breast biopsies.

5. Must be responsible for patient selection.
6. Must be responsible for qualify assurance activities including medical audit (tracking of number of biopsies, cancers found, benign lesions, biopsies needing repeat and complications).
7. Must be responsible for oversight of all quality control.
8. Must be responsible for the supervision of the radiologic technologist and the medical physicist.
9. Must be responsible for ~~postbiopsy~~ post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least ~~480~~ 240 mammograms per year in consultation with a physician who is qualified according to 41.6(3)"b".
2. Perform at least 12 ~~mammographically~~ stereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.
3. Obtain at least three hours of Category 1 CME in ~~mammographically~~ stereotactically guided breast biopsy every three years.

Amend subrule **41.7(4)** as follows:

41.7(4) Medical physicist.

a. Must be qualified according to 41.6(3)"c."
b. Must meet the following initial requirements:

(1) Prior to July 1, 1998, have performed three hands-on ~~mammographically~~ stereotactically guided breast biopsy system physics surveys; or one hands-on ~~mammographically~~ stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)"a" and 41.7(4)"b."

(2) On or after July 1, 1998, have one hands-on ~~image~~ stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified to perform ~~mammographically~~ stereotactically guided breast biopsy system physics surveys. Have at least one ~~mammographically~~ stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met; and three hours of continuing education in ~~mammographically~~ stereotactically guided breast biopsy system physics every three years after the initial qualifications are met.

Amend subrule **41.7(5)** as follows:

41.7(5) Radiologic technologist.

a. Must be qualified according to 41.6(3)"d."
b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a qualified physician or technologist.
(2) Three hours of continuing education in ~~mammographically~~ stereotactically guided breast biopsy.

c. Thereafter, an average of at least 12 ~~mammographically~~ stereotactically guided breast biopsies per year after initial qualifications are met.

d. Three hours of continuing education in ~~mammographically~~ stereotactically guided breast biopsy every 3 years after initial qualifications are met.

Amend subrule **41.7(7)** as follows:

41.7(7) Quality assurance program.

a. The facility shall have an equipment quality assurance program specific to ~~image~~ stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

Amend subrule **41.7(8)** as follows:

41.7(8) Equipment standards.

a. Be specifically designed for ~~mammographically~~ stereotactically guided breast biopsy.

Amend **641¾ Chapter 41**, Appendix A, the first paragraph, as follows:

In order for the agency to provide an evaluation~~, technical advice, and official approval~~ and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

Amend subrule **42.1(2)**, definitions of "Chest," "Diagnostic radiographer," "Simulation radiography," and "Simulation therapist," as follows:

"Chest" is defined as lung fields including the cardiac shadow, as taught in the approved limited radiography curriculum. Radiography of the shoulder, clavicle, scapula, ribs, thoracic spine and sternum for diagnostic evaluation of these body structures or chest radiography using anything other than a vertical cassette holder is not allowed under this body part classification for limited diagnostic radiographers. Limited radiographers already approved in "chest" radiography may perform oblique, apical lordotic, and decubitus chest views under this definition upon completion of additional training approved by this agency.

"Diagnostic radiographer" means an individual, other than a licensed practitioner or dental radiographer, who applies X-radiation to the human body for diagnostic purposes while under the supervision of a licensed practitioner or registered nurse practitioner pursuant to Iowa Code chapter 152. The types are as follows:

1. "General diagnostic radiographer" applies X-radiation to any part of the human body.
2. "Limited diagnostic radiographer" applies X-radiation to not more than ~~two body parts. Chest and extremity radiographic examinations are considered as~~

~~one body part.~~ three of the following body parts: chest, extremities (upper and lower), spine, or sinus.

"Simulation radiography" means the science and art of applying ~~X-radiation~~ radiation to human beings for the purpose of localizing treatment fields ~~and isotopes~~ and for treatment planning.

"Simulation therapist" means an individual, other than a physician, who applies ~~X-radiation~~ radiation to human beings for the purpose of localizing treatment fields ~~and isotopes~~ and for treatment planning.

Amend subrule **42.2(3)"g"**, paragraph **(2)**, as follows:

(2) Any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours and the fee required in 641—paragraph 38.8(6)"d" shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.

Amend subrule **42.3(3)** as follows:

a. All individuals seeking to perform diagnostic radiography must, in addition to subrule 42.3(1), take and satisfactorily pass a written examination within ~~one year~~ six months of the date of the initial certification. Examination must include the following subject matter for each category of radiographer:

Amend subrule **42.4(4)**, paragraph **"a"** as follows:

a. Students enrolled in and participating in an approved program or approved course of study for nuclear medicine technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radioactive material to a human being while under the supervision of a licensed physician who appears as an authorized user on an Iowa, agreement state, or NRC radioactive materials license. Clinical experience must be directly supervised by a certified nuclear medicine technologist or by a physician who appears as an authorized user on an Iowa or NRC radioactive materials license. Quality assurance and quality control experience may be directly supervised by a nuclear pharmacist who appears as an authorized user on an Iowa, U.S. Nuclear Regulatory Commission, or agreement state radioactive materials license.

Amend subrule **45.1(1)**, introductory paragraph, as follows:

45.1(1) Purpose and scope. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other

applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 9, 2001~~ July 4, 2001.

Amend subrule **45.1(2)** by amending the following definition:

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera), or any other industrial system whereby a permanent or semi-permanent image is recorded on an image receptor by action of ionizing radiation.

Amend subrule **45.1(1)** as follows:

45.1(1) Purpose and scope. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapter 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 1999~~May 9, 2001.

Amend subrule **45.1(10)"g,"** subparagraph **(1)** as follows:

(1) I.D. Card.

1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10)"b" and the examination prescribed in 45.1(10)"f"(2) or an equivalent examination. ~~Certification by a certifying entity in accordance with 10 CFR 34.43(a)(1) meets the examination requirements of 45.1(10)"f"(2) but not the requirements of 45.1(10)"b"(1).~~

Amend subrule **45.1(10)** by adopting **new** paragraph as follows:

j. Reciprocity.

(1) Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category and class issued by a certifying entity as defined in 45.1(2).
2. The requirements and procedures of the certifying entity issuing the certification require the same or comparable certification standards as those required by 45.10(1)"a" through "e;" and
3. The individual submits a legible copy of the certification to the agency prior to entry into Iowa.

(2) Enforcement actions with the agency, another agreement state, or the U.S. Nuclear Regulatory Commission, or any sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(3) Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 45.1(10)"b."

Amend subparagraph **45.2(6)"a"(2)** as follows:

(2) Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of ~~two~~ three years after the evaluation.

Amend paragraph **45.2(6)"b"** as follows:

b. Certified and certifiable cabinet X-ray systems ~~designed to exclude individuals from the interior of the cabinet~~ are exempt from the requirements of this chapter except that:

Amend subrule **45.4(1)** by amending paragraph "**b**" and adding **new** paragraph "**c**":

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C). ~~The requirements of 45.1(10) do not apply.~~

c. The requirements of 45.1(10) do not apply to non-radiographic uses.

Amend paragraph **45.4(3)"a"** as follows:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

Amend subrule **45.4(6)** by adding the following the **new** paragraph:

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of 45.1(10).

Amend paragraph **45.4(6)"c"** as follows:

c. Along with the audit required in 641—subrule 40.10(3), each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed ~~12~~six months. If an operator has not participated in an accelerator operation for more than ~~12~~six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation. Records of the audits shall be maintained by the registrant for the agency inspection for three years from the date of the audit.

Amend paragraph **45.4(10)"c"** as follows:

c. All safety and warning devices, including interlocks, shall be checked for proper operation intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency for three years.

Amend paragraph **45.4(10)"d"** as follows:

d. All incidents ~~whereby~~ in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or, if applicable, the radiation safety committee. Documentation shall be maintained for inspection by the agency for three years.

Amend paragraph **45.4(11)"b"** as follows:

b. Accelerator facilities ~~registered pursuant to 45.4(3)"a"~~ shall survey with a radiation detection instrument at intervals not to exceed ~~three~~ 12 months. Records of this survey shall be maintained for agency review for three years.

Amend paragraph **45.4(11)"c"** as follows:

c. Accelerator facilities registered or licensed pursuant to 45.4(3)"a" shall survey for removable contamination at intervals not to exceed six months to determine the degree of contamination.

Amend paragraph **45.4(11)"e"** as follows:

e. Accelerator facilities registered or licensed pursuant to 45.4(3)"a" shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

Amend paragraph **45.4(11)"h"** as follows:

h. Whenever applicable, accelerator facilities registered or licensed pursuant to 45.4(3)"a" shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

Amend rule **641¾46.1(136D)**, first unnumbered paragraph, as follows:

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 10, 2000~~ January 1, 2001.

Amend subrule 46.4(6) by adopting the following **new** paragraph:

d. Once a permit to operate has been suspended or revoked, it may be reinstated upon receipt of a fee of $50 and completion of all other agency requirements. This fee is in addition to other applicable fees.

Amend subrule **46.4(7)**, paragraph **"b,"** by adopting the following **new** subparagraph:

(4) A penalty fee of $25 per facility may be assessed for the following:

1. Failure to respond to a notice of violation within 30 days of the date of the inspection.
2. Failure to correct violations cited during the inspection.

Amend subrule **46.5(9)**, paragraph "**j**," as follows:

j. When a tanning device is being used, no other person shall be allowed to remain in the tanning device area ~~unless protective eyewear is worn~~.

Amend subrule 46.5(9), by adopting **new** paragraph "k" as follows:

k. No person or facility shall advertise or promote tanning packages labeled as "unlimited" unless tanning frequency limits set by the manufacturer are included in advertisements.